IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION, Plaintiff, v. CYCLACEL PHARMACEUTICALS, INC., Defendant.	C. A. No. 10-348-GMS
CYCLACEL PHARMACEUTICALS, INC., Counterclaim-Plaintiff, v. CELGENE CORPORATION, Counterclaim-Defendant.	

CYCLACEL'S MOTION TO (1) STRIKE CELGENE'S EXTRINSIC EVIDENCE (EXPERT DECLARATION AND REFERENCES) AND UNAUTHORIZED REVISED CLAIM CONSTRUCTIONS FROM CELGENE'S OPENING CLAIM CONSTRUCTION BRIEF AND (2) SHORTEN TIME FOR RESPONSE TO MEET JANUARY 31, 2013 DEADLINE FOR OPPOSITION BRIEFS

Cyclacel Pharmaceuticals, Inc. ("Cyclacel") respectfully requests that the Court strike Celgene's submission of (a) its unauthorized extrinsic evidence (an expert declaration, sixteen exhibits cited therein, and Ex. 26 attached to the Oskoui Declaration) (D.I. 108, 109) and (b) its untimely, revised claim constructions – both included in Celgene's Opening Claim Construction Brief (D.I. 107). Celgene did not notify, much less ask permission from, the Court to file these unauthorized papers.

I. Dr. Croft Expert Declaration

Ignoring the express directive of this Court, Celgene submitted an opening claim construction brief relying on an expert declaration from Michael Croft, PhD that relied on sixteen exhibits, none of which are of record in this case. The unauthorized Croft declaration is not a neutral technology tutorial. It is an advocacy expert declaration providing "his expert opinions" "in support of Celgene's proposed claim construction." (D.I. 108, Croft Decl. ¶¶ 3, 4) Indeed, the Croft declaration repeatedly interprets "the scope of the patents-in-suit" and their "teach[ings]. " (*See* D.I. 108, Croft Decl. ¶¶ 5, 9, 11) Celgene's submission ignores this Court's explicit admonition against citation to extrinsic evidence:

> THE COURT: ... Counsel who have not appeared in front of me before. Let me advise you, with regard to the Markman hearing, unless you have some very, very good reason for asking me to entertain extrinsic evidence, reasons that are typically endorsed by the Federal Circuit Court of Appeals, **this judge does not typically hear extrinsic evidence. Am I clear on that?**
> UNIDENTIFIED SPEAKER: Yes, Your Honor.
> THE COURT: **I am being stern about that**, because of late there seems to be some slippage out there in the bar. I am pointing my daggers at the Delaware counsel on this line, who need to be advising your out-of-town counsel that **Judge Sleet typically doesn't hear extrinsic evidence**. It's not that he won't hear it, but he has to have a good reason for hearing it.
> Am I making myself clear to Mr. Rovner and Mr. Cottrell?
> **Mr. Rovner: Yes, Your Honor.** (Ex. A, 02/01/12 Hearing Tr. at 7) (emphasis added)

Cyclacel stayed faithful to the Court's admonition to rely strictly on the intrinsic record and to avoid extrinsic evidence.

Even assuming, *arguendo*, that the Court would consider extrinsic evidence, Dr. Croft's declaration should be stricken because Dr. Croft does not define the qualifications of a skilled artisan, much less allege that he is interpreting the patents-in-suit through the eyes of a skilled artisan. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (claim construction is done from the perspective of one of ordinary skill in the art.) Thus, Dr. Croft's declaration is irrelevant to claim construction, is a violation of this Court's directive not to rely on extrinsic evidence for claim construction, and should be stricken together with all of the extrinsic references it relies upon. *See In re: Alfuzosin Hydrochloride Patent Litigation*, 08-md-01941-GMS, 04/28/2009 (Ex. B at p. 19) ("Order Striking 78 Declaration filed by Sanofi-Aventis … The court does not take extrinsic evidence in determining claim construction.").

II. Celgene's Untimely and Unauthorized Revised Claim Constructions

On November 20, 2012 , pursuant to the Court's Scheduling Order, the parties submitted their proposed claim constructions in their Joint Claim Construction Chart ("JCCC") (D.I. 75). Significant effort went into the parties' submission of the JCCC. The parties dutifully exchanged multiple drafts and met and conferred in order to reduce the number of terms and the magnitude of their differences. Cyclacel treated the constructions included in the JCCC as final following the Court's directive:

> THE COURT: … Make sure that the submission of the joint claim construction chart on November 20, you need to know, that's your final chart and those are your positions that you will be held to, in terms of your Markman positions. That chart needs to have citations to the intrinsic record. (02/01/12 Hearing Tr. at 7)

Celgene did not. On January 8, 2013 at 10 PM EST, just two days before the parties' opening briefs were due, and over a month and a half after the parties filed the final JCCC (D.I. 75), Celgene unilaterally proposed new and different constructions for certain claim terms such as "hyperproliferative skin disease" and "inflammatory disease." For example, with respect to hyperproliferative skin disease:

'479 Claim 9: "treating a hyperproliferative skin disease"

Celgene JCCC Construction (D.I. 75)	Celgene Jan. 8th Modified Construction (Redlined) (No Leave of Court)
"hyperproliferative skin disease" - Disease characterized by an abnormally high rate of skin cell proliferation	"hyperproliferative skin disease" - ~~Disease~~Skin disease characterized by an abnormally high rate of ~~skin cell~~

	proliferation of lymphocytes responding to the body's exposure to antigens

Thus, as the above chart shows, Celgene completely abandoned its previous JCCC construction that hyperproliferative skin disease meant a hyperproliferation of "skin cell[s]" and now asserts that it means a hyperproliferation of "lymphocytes."[1] Furthermore, those lymphocytes have additional restrictions: they are lymphocytes "responding to the body's exposure to antigens." Notwithstanding its untimely and one-sided proposal, Celgene tried to style its drastic, wholesale change in its constructions—from skin cells to lymphocytes—as "an attempt to narrow the issues." (D.I. 109, Ex. 23). Celgene's changed, unauthorized construction, however, injects multiple new issues into the claim construction.

Despite Cyclacel's rejection of this conduct, Celgene, without leave of Court, employed all of its new January 8, 2013 constructions in its opening Markman brief. (D.I. 107 at 14, 16, 12)[2] Cyclacel respectfully submits that the Court should not permit this untimely and unauthorized self-help by Celgene.

III. The Court's Guidance Is Needed Prior to the Filing of the Reply Claim Construction Briefs

In light of the fast approaching deadline of January 31, 2013 for the filing of reply claim construction briefs and Cyclacel's urgent need to have guidance on whether it has to submit a

[1] It is undisputed that lymphocytes are not skin cells.

[2] In addition, Celgene proposed to accept Cyclacel's constructions of the words "proliferation" and "growth" (but not of the entire claim elements where they are used). Given the piecemeal nature of Celgene's proposal, its untimeliness, and the absence of leave of Court, Cyclacel declined this proposal. (Ex. C, 01/11/13 Letter from J. Bauer to N. Oskoui) Tellingly, Celgene did not include this letter in its Markman submission. Now, in the spirit of cooperation and after having seen Celgene's claim construction brief, Cyclacel agrees to accept Celgene's adoption of Cyclacel's proposed constructions of the words "proliferation" and "growth" (and that the word "inflammation" needs no construction). All other Celgene's January 8th constructions deviating from the JCCC are unauthorized attempts to change its JCCC constructions without leave of Court.

declaration of its own expert to challenge the unauthorized Croft declaration and publications, the Court is respectfully requested to shorten Celgene's time to file a response to this motion to 3 business days (to be filed no later than Friday January 18, 2013 at 5:00pm ET).

IV. CONCLUSION

For the foregoing reasons, it is respectfully requested that the Court order expedited briefing as set forth above and that the Court strike (1) Dr. Croft's declaration and associated extrinsic publications it relies upon and Ex. 26 to the Oskoui Declaration, and (2) Celgene's modified constructions not included in the JCCC (D.I. 75). Further, the Court should order Celgene to refile (but not rewrite) a corrected opening Markman brief in 3 days by deleting from it all references to the Croft declaration, extrinsic publications, and claim constructions not included in the JCCC (with the exception of Celgene adopting Cyclacel's constructions for the words "proliferation," "growth," and "inflammation").

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Dated: January 16, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2013, I caused to be served by **electronic mail** copies of the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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